

# Zagallo Capsules Drug Use Investigation (202029)

**First published:** 08/03/2016

**Last updated:** 18/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/48259>

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### EU PAS number

EUPAS12703

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### Study ID

48259

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### DARWIN EU® study

No

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### Study countries

Japan

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## Study description

This investigation will be implemented to collect and evaluate the information on safety and effectiveness of Zagallo Capsules in male patients with androgenetic alopecia in daily clinical practice.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[GlaxoSmithKline \(GSK\)](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

[Multiple centres: 800 centres are involved in the study](#)

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor  
GSK Clinical Disclosure Advisor

### Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

### Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 24/09/2014

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### Study start date

Planned: 30/03/2016

Actual: 22/07/2016

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### Date of final study report

Planned: 30/09/2019

Actual: 13/12/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Disease /health condition

Human medicinal product

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

This investigation is implemented to collect and evaluate the information on safety and effectiveness of Zagallo Capsules in male patients with androgenetic alopecia in daily clinical practice.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational post-marketing surveillance

## Study drug and medical condition

**Name of medicine, other**

zagallo capsules

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**Medical condition to be studied**

Androgenetic alopecia

## Population studied

## **Short description of the study population**

Male patients aged 18 years or older diagnosed with androgenetic alopecia (AGA) receiving Zagallo for the first time for hair growth, hair restoration and prevention of hair loss under routine clinical practice from May 2016 to January 2019.

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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Special population of interest**

Hepatic impaired

Immunocompromised

Other

Renal impaired

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### **Special population of interest, other**

Patients with androgenetic alopecia

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### **Estimated number of subjects**

4000

## **Study design details**

## Outcomes

Information regarding the safety and efficacy of Zagallo Capsules under the actual post-marketing use conditions of the product.

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## Data analysis plan

Patient disposition ADR related items Response rate based on the global assessment of effectiveness Factors considered influential on safety and effectiveness, odds ratio and 95% confidence interval thereof shall be calculated for the factors considered influential.

## Documents

### Study results

[gsk-202029-clinical-study-report-redact.pdf](#)(975.57 KB)

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## Data management

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No